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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/612,357	07/07/2000	Ying Sun	J&J-1930	8243

7590

11/05/2002

Audley A Ciamporcero Jr Esq
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

EXAMINER

WILLIAMSON, MICHAEL A

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 11/05/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/612,357

Applicant(s)

SUN ET AL.

Examiner

Michael A. Williamson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Pending Claims

The pending claims in the instant application are 1-20. The only independent claim is 1.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 22, 2002 has been entered.

Claim Rejections - 35 USC § 103

2. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (U.S. Patent 6,245,347) in view of Fujiwara (U.S. Patent 4,205,957).

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Zhang et al. discloses an exothermic device for topically delivering an active agent comprising a liquid reservoir, a heating element in contact with the reservoir containing, an oxygen permeable outer layer in communication with the heating element, an active agent and water impermeable membrane separating the active agent from the heating element wherein the properties and the materials meet the instant claimed limitations of the instant claimed invention. The device is used to transdermally apply medicaments (see Abstract, col. 1, lines 14-19, Summary of the Invention and col. 12, line 11 through col. 21, line 15). Zhang does not disclose that the liquid reservoir is a capsule comprising water and a salt, the inorganic powder is that of the instant claimed invention or that active agent is for the treatment of acne.

Zhang et al. does disclose an inorganic powder that is oxidizable giving off heat and the inorganic powders of the instant claimed invention are also known oxidizable powders known to react the same (see col. 8, line 3 through col. 9, line 11). Additionally, Zhang et al. discloses that the exothermic device may be used to administer a variety of drugs which encompasses a drug for treating acne (see col. 20 line 65 to col. 21, line 15). Fujiwara discloses a heating element, a controlled heating device, comprising a liquid reservoir that is a capsule containing water and a salt (see col. 2, line 3 through col. 7, line 19). The advantage of the heating element taught by

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Fujiwara is that a longer heating duration is obtained and longer storage. Therefore, it would have been obvious to one of ordinary skill in the art to use the teachings of Fujiwara in the invention of Zhang et al. to make the device of the instant claimed invention since the instant claimed inorganic powders are known to be functionally equivalent to that used in the art, that drugs used in the treatment of acne are suggested in the art and the resulting structure yields longer heating duration and longer storage in the absence of a factual showing to the contrary or a showing of unexpected results.

Response to Arguments

3. Applicant's arguments filed July 22, 2002 have been fully considered but they are not persuasive.

Applicant argues that in order to rely on a reference for the basis for rejection of Applicant's invention, the reference must either be in the field of Applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the invention was concerned (see page 2, 2nd full paragraph). The primary reference teaches administering an active agent transdermally using a heating generating chamber (see Abstract). The secondary reference teaches a heating element for use in heater poultices (see Abstract). In response to applicant's argument that the secondary

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reference is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the secondary reference is directed to a heater poultice which is a heated device applied to warm, moisten, or stimulate a sore or inflamed part of the body. Applicant additionally argues that the asserted advantage of longer heating duration in Fujiwara is not stated to be a result of using a capsule, but rather the ingredients used to create the exothermic reaction. Fujiwara teaches using materials similar to those of the instant claimed invention. Since the materials are the same as those of the instant claimed invention it is asserted that the physical properties are the same in the absence of a factual showing to the same or a showing of unexpected results.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

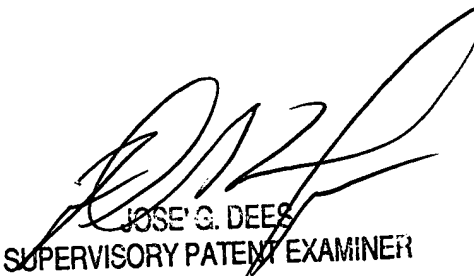
5.

Crystal Mall 1 Facsimile Center

A facsimile center has been established in Crystal Mall 1, room 7C10. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 308-4556. The new location should be used in all instances when faxing any correspondence to Group 1600. Use of the new Crystal Mall 1 center will facilitate rapid delivery of materials to the Group. The faxing of all papers must conform with the notice published in the Official Gazette, 1096 O.G. 30 (November 15, 1989).

6. Any inquiry concerning this communication or earlier communication from the examiner should be directed to Michael A. Williamson whose telephone number is (703) 308-1235.

Williamson021104
November 4, 2002


JOSE G. DEES
SUPERVISORY PATENT EXAMINER
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